

Remarks/Arguments

The Examiner has rejected Claims 1, 3-5, 10, 11 and 16-18 under 35 U.S.C. §102(b) as being anticipated by Nakajima et al. (JP 09315971).

Nakajima describes tablets containing terfenadine.

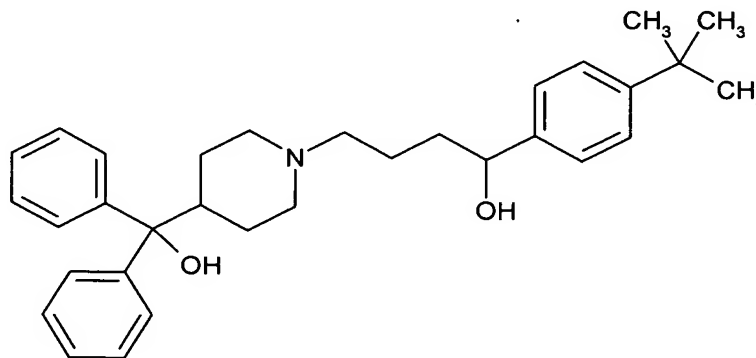
In contrast, Applicants' claims are limited to pharmaceutical compositions containing fexofenadine as the active ingredient. Thus, Applicants' invention as claimed is not identically disclosed in Nakajima.

The Examiner has rejected Claims 1, 2, 6-9 and 12-20 under 35 U.S.C. §103(a) as being unpatentable over Nakajima et al. (JP 09315971).

Nakajima describes tablets containing terfenadine, lactose, low-substituted hydroxypropyl cellulose, and precipitated calcium carbonate. According to Nakajima, terfenadine is present in an amount of 1 weight part; lactose is present in an amount of at least 1.3 weight parts; low-substituted hydroxypropyl cellulose is present in an amount of at least 0.45 weight parts; and precipitated calcium carbonate is present in an amount of at least 0.95 weight parts. All of the examples of formulations in Nakajima (7 formulations) require these ingredients in at least the minimum respective amounts.

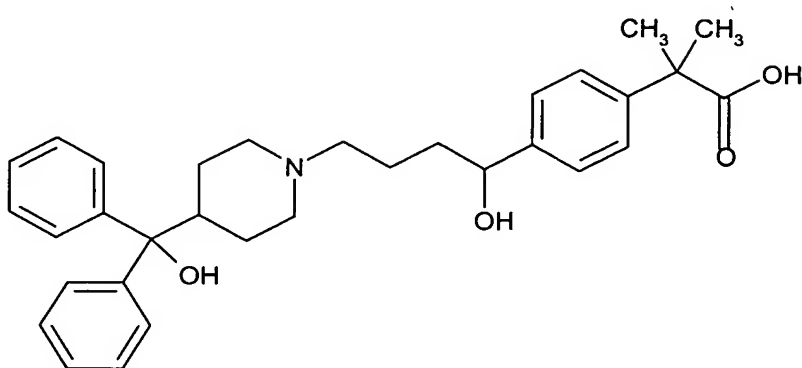
As stated in Nakajima, in paragraph 8, lines 11-18, tablets prepared containing a combination of low-substituted hydroxypropyl cellulose and precipitated calcium carbonate in a specific number of weight parts have substantially consistent dissolution and absorption values as compared to tablets obtained with preparations of prior art.

With regard to the active ingredient, according to the Merck Index, thirteenth edition, page 1635, terfenadine has terminal methyl groups, as shown in Figure 1.



Terfenadine

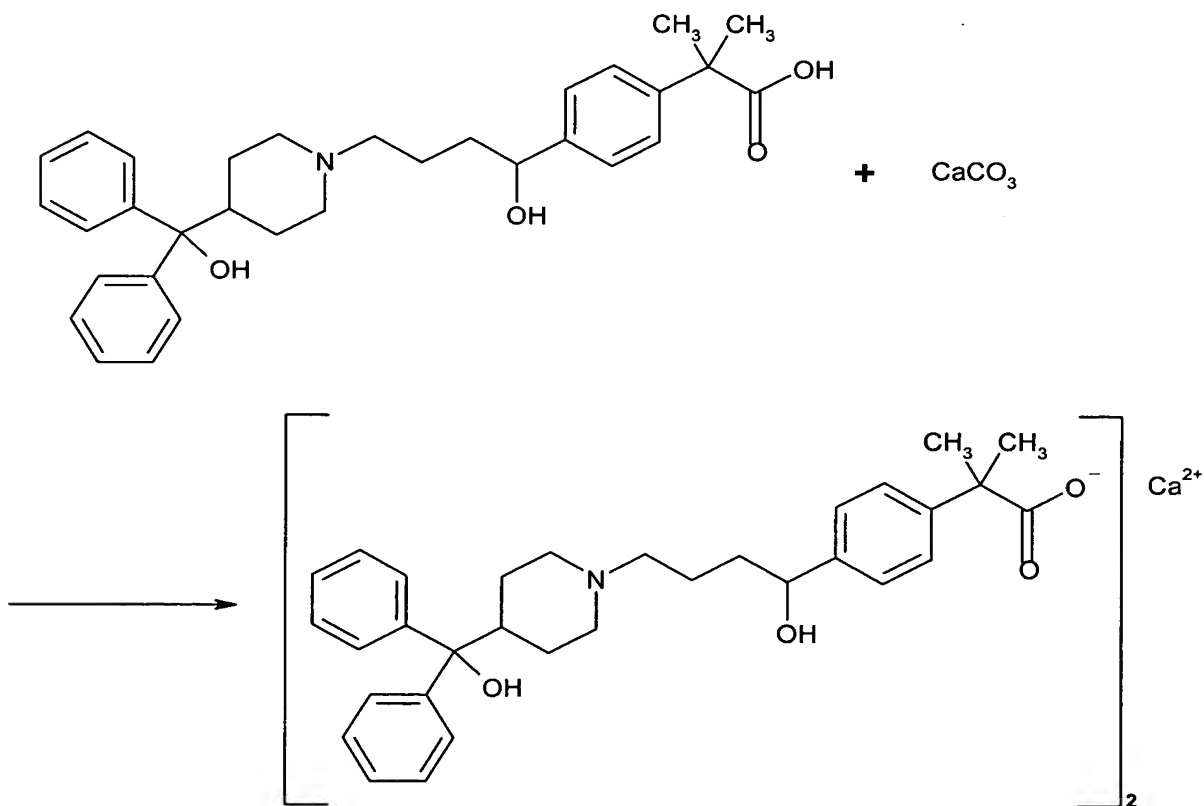
In contrast, according to the Merck Index, thirteenth edition, page 718, fexofenadine has a terminal carboxylic acid group, as shown in Figure 2.



Fexofenadine

Fexofenadine will react with calcium carbonate (CaCO_3), which is a base, to form a calcium salt of fexofenadine. In contrast, terfenadine which has terminal methyl groups will not react with calcium carbonate. The formation of the calcium salt of fexofenadine is especially likely in a wet granulation process, as described by Nakajima in paragraph 10, as compared to a dry compaction method for preparing tablets.

The formation of the calcium salt of fexofenadine may be illustrated as follows:



Calcium Salt of Fexofenadine

It is clear to one skilled in the art that the calcium salt of fexofenadine would have different dissolution, solubility, stability, compressibility, and absorption properties as compared to terfenadine which does not form a salt with calcium carbonate. Thus, Nakajima which describes calcium carbonate as an essential ingredient to be used with terfenadine, teaches away from using fexofenadine due to the formation of a calcium salt of fexofenadine which is not present when terfenadine is the active ingredient.

Moreover, by only teaching terfenadine as the active ingredient, Nakajima strongly suggests that substituting another active ingredient would produce unacceptable results. This is especially true in the case where the active ingredient is fexofenadine which has a terminal carboxylic acid group, as compared to terfenadine which has a terminal aliphatic group.

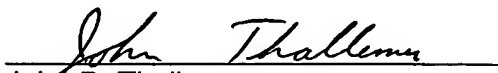
Applicants have amended independent Claims 1, 18 and 19 to replace the transition language "comprising" with "consisting essentially of". As a result, Applicants' claims are limited to fexofenadine, lactose, a low-substituted hydroxypropyl cellulose and other ingredients that do not materially affect the basic and novel characteristics of the claimed composition. Thus, applicants' claims, as amended, exclude calcium carbonate as taught by Nakajima.

It is important not confuse the calcium salt of fexofenadine with an acid addition salt of fexofenadine. An acid addition salt is formed by the addition of an acid, i.e., hydrochloric acid, to a base. A preferred acid addition salt of fexofenadine is fexofenadine hydrochloride. Applicants have amended independent Claims 1, 18, and 19 to specify that the pharmaceutically acceptable salts of fexofenadine are pharmaceutically acceptable "acid addition" salts thereof. Support is found in applicants specification, as originally filed, on page 3, in the first paragraph below the heading, "description of the invention", wherein applicants state that "fexofenadine may form a salt with various inorganic and organic acids".

It is requested that the Examiner reconsider the rejections in view of applicants' amendment and remarks and pass the application to issue.

Respectfully submitted,

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